### § 1005.10

### Subpart B—Inspection and Testing

#### § 1005.10 Notice of sampling.

When a sample of a product to be offered for importation has been requested by the Secretary, the District Director of Customs having jurisdiction over the shipment shall, upon the arrival of the shipment, procure the sample and shall give to its owner or consignee prompt notice of the delivery or of the intention to deliver such sample to the Secretary. If the notice so requires, the owner or consignee will hold the shipment of which the sample is typical and not release such shipment until he receives notice of the results of the tests of the sample from the Secretary, stating that the product is in compliance with the requirements of the Act. The District Director of Customs will be given the results of the tests. If the Secretary notifies the District Director of Customs that the product does not meet the requirements of the Act, the District Director of Customs shall require the exportation or destruction of the shipment in accordance with customs laws.

#### § 1005.11 Payment for samples.

The Department of Health and Human Services will pay for all import samples of electronic products rendered unsalable as a result of testing. or will pay the reasonable costs of repackaging such samples for sale, if the samples are found to be in compliance with the requirements of Subchapter C-Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968). Billing for reimbursement shall be made by the owner or consignee to the Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857. Payment for samples will not be made if the sample is found to be in violation of the Act, even though subsequently brought into compliance pursuant to terms specified in a notice of permission issued under § 1005.22.

[73 FR 34860, June 19, 2008]

# Subpart C—Bonding and Compliance Procedures

### §1005.20 Hearing.

- (a) If, from an examination of the sample or otherwise, it appears that the product may be subject to a refusal of admission, the Secretary shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony unless the owner or consignee indicates his intention to bring the product into compliance. Upon timely request, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility of the article and may be introduced orally or in writing.
- (b) If the owner or consignee submits or indicates his intention to submit an application for permission to perform such action as is necessary to bring the product into compliance with the Act, such application shall include the information required by \$1005.21.
- (c) If the application is not submitted at or prior to the hearing, the Secretary may allow a reasonable time for filing such application.

### § 1005.21 Application for permission to bring product into compliance.

Application for permission to perform such action as is necessary to bring the product into compliance with the Act may be filed only by the owner, consignee, or manufacturer and, in addition to any other information which the Secretary may reasonably require, shall:

- (a) Contain a detailed proposal for bringing the product into compliance with the Act:
- (b) Specify the time and place where such operations will be effected and the approximate time for their completion; and
- (c) Identify the bond required to be filed pursuant to §1005.23.

### § 1005.22 Granting permission to bring product into compliance.

(a) When permission contemplated by §1005.21 is granted, the Secretary shall

### Food and Drug Administration, HHS

notify the applicant in writing, specifying:

- (1) The procedure to be followed;
- (2) The disposition of the rejected articles or portions thereof:
- (3) That the operations are to be carried out under the supervision of a representative of the Department of Health and Human Services;
- (4) A reasonable time limit for completing the operations; and
- (5) Such other conditions as he finds necessary to maintain adequate supervision and control over the product.
- (b) Upon receipt of a written request for an extension of time to complete the operations necessary to bring the product into compliance, the Secretary may grant such additional time as he deems necessary.
- (c) The notice of permission may be amended upon a showing of reasonable grounds thereof and the filing of an amended application for permission with the Secretary.
- (d) If ownership of a product included in a notice of permission changes before the operations specified in the notice have been completed, the original owner will remain responsible under its bond, unless the new owner has executed a superseding bond on customs Form 7601 and obtained a new notice.
- (e) The Secretary will notify the District Director of Customs having jurisdiction over the shipment involved, of the determination as to whether or not the product has in fact been brought into compliance with the Act.

### § 1005.23 Bonds.

The bond required under section 360(b) of the Act shall be executed by the owner or consignee on the appropriate form of a customs single-entry bond, customs Form 7551 or term bond, customs Form 7553 or 7595, containing a condition for the redelivery of the shipment or any part thereof not complying with the laws and regulations governing its admission into the commerce of the United States upon demand of the District Director of Customs and containing a provision for the performance of any action necessary to bring the product into compliance with all applicable laws and regulations. The bond shall be filed with the District Director of Customs.

## § 1005.24 Costs of bringing product into compliance.

The costs of supervising the operations necessary to bring a product into compliance with the Act shall be paid by the owner or consignee who files an application pursuant to \$1005.21 and executes a bond under section 360(b) of the Act. Such costs shall include:

- (a) Travel expenses of the supervising officer:
- (b) Per diem in lieu of subsistence of the supervising officer when away from his home station, as provided by law;
- (c) Service fees: (1) The charge for the services of the supervising officer, which shall include administrative support, shall be computed at a rate per hour equal to 266 percent of the hourly rate of regular pay of a grade GS-11/4 employee, except that such services performed by a customs officer and subject to the provisions of the act of February 13, 1911, as amended (sec. 5, 36 Stat. 901, as amended (19 U.S.C. 267)), shall be calculated as provided in that act.
- (2) The charge for the services of the analyst, which shall include administrative and laboratory support, shall be computed at a rate per hour equal to 266 percent of the hourly rate of regular pay of a grade GS-12/4 employee.
- (3) The rate per hour equal to 266 percent of the equivalent hourly rate of regular pay of the supervising officer (GS-11/4) and the analyst (GS-12/4) is computed as follows:

	Hours
Gross number of working hours in 52 40-hour weeks	2,080
Less: Nine legal public holidays—New Years Day, Washington's Birthday, Memorial Day, Inde- pendence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and	
Christmas Day Annual Leave—26 days Sick Leave—13 days	72 208 104
Total	384
Net number of working hours	1,696
Gross number of working hours in 52 40-hour weeks	2,080
and health benefits computed at 81/2% of annual rate of pay of employee	176
Equivalent annual working hours	2,256